

**K853216 MASTER ENDOMET BIOPSY KIT W/PLAS CURE
3,4MM-4003,4**Apr 2, 1986
244 days to decisionK853216 · Product code: **HHK** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k853216/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Curette, Suction, Endometrial (and Accessories) (HHK)
Date received	Aug 1, 1985
Decision date	Apr 2, 1986
Days to decision	244 days
Third-party review	No

APPLICANT

Company	Gyneco, Inc.
Location	Mchenry, IL, US
Contact	JANE AOYAGI
510(k) history	5 submissions · 5 cleared · 1984-1986

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k853216/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 30, 2026